

Dysport (abobotulinumtoxinA) Injection Clinical Update

Clinical Update: Ipsen announces updated indication for Dysport (abobotulinumtoxinA) for the treatment of spasticity in children

FDA approval date: July 08, 2020

Dysport (abobotulinumtoxinA) is an acetylcholine release inhibitor and neuromuscular blocking agent. Dysport is an injectable form of botulinum toxin type A (BoNT-A), which is isolated and purified from Clostridium bacteria producing BoNT-A. It is supplied as a lyophilized powder. Dysport has approved indications in the United States for the treatment of adults with cervical dystonia (CD) and for the treatment of spasticity in adult patients. Dysport is also the first FDA-approved botulinum toxin for the treatment of both upper and lower limb spasticity in children two years of age or older.

Dysport® (abobotulinumtoxinA) for injection is indicated for the treatment of:

- Spasticity in patients 2 years of age and older
- Cervical dystonia in adults
- Temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults < 65 years of age

Dysport was first FDA-approved in 2016 for pediatric lower limb spasticity, Ipsen was granted Orphan Drug exclusivity for pediatric patients whose lower limb spasticity was caused by cerebral palsy (CP). Similarly, in 2019, Dysport received FDA approval for the treatment of upper limb spasticity in children two years of age and older, excluding upper limb spasticity caused by CP, due to Orphan Drug exclusivity granted to another manufacturer. Ipsen has worked with the FDA and this manufacturer to selectively waive their respective exclusivities to better support patient care. As a result, Dysport is now FDA-approved to treat both upper and lower limb spasticity in pediatric patients two years of age and older, including spasticity caused by cerebral palsy.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.